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Divisional Of:

Applicants: Baskaran Chandrasekar, et al.
Serial No.: 10/088,405
Filed: March 11, 2002
For: LOCAL DELIVERY OF 17-BETA ESTRADIOL
FOR PREVENTING VASCULAR INTIMA
HYPERPLASIA AND FOR IMPROVING
VASCULAR ENDOTHELIUM FUNCTION AFTER
VASCULAR INJURY
Group Art Unit: 3762
Examiner: --

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. 1.98, enclosed herewith is a list of documents which the Applicants in the above-identified patent application wish to bring to the attention of the Examiner for consideration in connection with the examination on the merits of this patent application. As this information duplicates information presented in related case Serial No. 10/088,405, Applicants have not provided copies of the documents.

Other Documents

Akishita, M., et al., "Estrogen Inhibits Cuff-induced Intima Thickening of Rat Femoral Artery: Effects

on Migration and Proliferation of Vascular Smooth Muscle Cells," Atherosclerosis 130:1-10, 1997.

Albuquerque, M.L., et al., "Basic Fibroblast Growth Factor Release by Human Coronary Artery Endothelial Cells is Enhanced by Matrix Proteins, 17-beta Estradiol and a PKC Signaling Pathway," Exp. Cell Res. 245(1):163-169, 1998.

Asahara, T., et al., "Local Delivery of Vascular Endothelial Growth Factor Accelerates Reendothelialization and Attenuates Intima Hyperplasia in Balloon-injured Rat Carotid Artery," Circulation 91(11):2793-2801, 1995.

Bauriedel, G., et al., "Migratory Activity of Human Smooth Muscle Cells Cultivated from Coronary and Peripheral Primary and Restenotic Lesions Removed by Percutaneous Atherectomy," Circulation 85(2):554-564, 1992.

Bonan, R., et al., "Coronary Restenosis: Evaluation of a Restenosis Injury Index in a Swine Model," Am. Heart J. 126(6):1334-1340, 1993.

Brewster, M.E., et al., "Use of 2-hydroxypropyl-beta-cyclodextrin as a Solubilizing and Stabilizing Excipient for Protein Drugs," Pharm. Res. 8(6):792-795, 1991.

Chandrasekar, B. and Tanquay, J.F., "Local Delivery of 17-beta Estradiol Decreases Neointima Hyperplasia

Following Coronary Angioplasty in Porcine Model,"
(submitted for publication).

Chandrasekar, B., et al., "Coronary Artery
Endothelial Protection Following Local Delivery of 17-
beta Estradiol During Balloon Angioplasty: A Potential
New Pharmacological Approach to Improve Long-term Outcome
of Angioplasty," J. Am. Coll. Cardiol. 35(2):58A, 2000.

Chen, S.J., et al., "Estrogen Reduces Myointimal
Proliferation after Balloon Injury of Rat Carotid
Artery," Circulation 93(3):577-584, 1996.

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49(3):327-333, 1983.

Collins, P., et al., "Hemoglobin Inhibits
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85, 1993.

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Dangas, G and Fuster, V., "Management of Restenosis after Coronary Intervention," Am. Heart J. 132(2):428-436, 1996.

Doenicke, A., et al., "A Comparison of Two Formulations for Etomidate, 2-hydroxypropyl-beta-cyclodextrin (HPCD) and Propylene Glycol," Anesth. Analg. 79:933-939, 1994.

Fischell, T.A., et al., "Coronary Artery Vasoconstriction Routinely occurs after Percutaneous Transluminal Coronary Angioplasty: A Quantitative Arteriographic Analysis," Circulation 78(6):1323-1334, 1988.

Foegh, M.L., et al., "Estradiol Inhibition of Arterial Neointima Hyperplasia after Balloon Injury," J. Vasc. Surg. 19(4):722-726, 1994.

Frijlink, H.W., et al., "The Pharmacokinetics of Beta-cyclodextrin and 2-hydroxypropyl-beta-cyclodextrin in the Rat," Pharm. Res. 7(12):1248-1252, 1990.

Furchtgott, R.F. and Zawadzki, J.V., "The Obligatory Role of Endothelial Cells in the Relaxation of Arterial Smooth Muscle by Acetylcholine," Nature 288:373-376, 1980.

Geary, R.L.; et al., "Conjugated Equine Estrogens Inhibit Progression of Atherosclerosis but have no Effect on Intima Hyperplasia or Arterial Remodeling Induced by Balloon Catheter Injury in Monkeys," J. Am. Coll. Cardiol. 31(5):1158-1164, 1998.

Gilligan, D.M., et al., "Effects of Physiological Levels of Estrogen on Coronary Vasomotor Function in Postmenopausal Women," Circulation 89(6):2545-2551, 1994.

Hayashi, Y., et al., "Functional and Anatomical Recovery of Endothelium after Denudation of Coronary Artery," Am. Physiol. Soc. H1081-H1090, 1988.

Hayashi, T., et al., "Estrogen Increases Endothelial Nitric Oxide by a Receptor-mediated System," Biochem. Biophys. Res. Commun. 214(3):847-855, 1995.

Hishikawa, K., et al., "Up-regulation of Nitric Oxide Synthase by Estradiol in Human Aortic Endothelial Cells," FEBS Let. 360:291-293, 1995.

Hoon, T.J., et al., "Bioequivalence of a 17-beta Estradiol Hydroxypropyl-beta-cyclodextrin Complex in Postmenopausal Women," J. Clin. Pharmacol. 33:1116-1121, 1993.

Hyder, S.M., et al., "Uterine Expression of Vascular Endothelial Growth Factor is Increased by Estradiol and Tamoxifen," Cancer Res. 56(17):3954-3960, 1996.

Iafrati, M.D., et al., "Estrogen Inhibits the Vascular Injury Response in Estrogen Receptor α -deficient Mice," Nat. Med. 3(5):545-548, 1997.

Karas, R.H., et al., "Human Vascular Smooth Muscle Cells Contain Functional Estrógen Receptor," Circulation 89(5):1943-1950, 1994.

Karas, S.P., et al., "Coronary Intimal Proliferation after Balloon Injury and Stenting in Swine: An Animal Model of Restenosis," J. Am. Coll. Cardiol. 20(2):467-474, 1992.

Kauffman, R.F., et al., "Comparative Effects of Local vs. Systemic Administration of Estrogen upon Vascular Responses to Balloon Injury," Circulation 92(8):1628, 1995.

Kawano, H., et al., "Gender Differences in Improvement of Endothelium-dependent Vasodilation after Estrogen Supplementation," J. Am. Coll. Cardiol. 30(4):914-919, 1997.

Keaney, J.F., et al., "17-Beta-estradiol Preserves Endothelial Vasodilator Function and limits Low-density Lipoprotein Oxidation in Hypercholesterolemic Swine," Circulation 89(5):2251-2259, 1994.

Kim-Schulze, S., et al., "Expression of an Estrogen Receptor by Human Coronary Artery and Umbilical Vein Endothelial Cells," Circulation 94(6):1402-1407, 1996.

Kim-Schulze, S., et al., "Estrogen Stimulates Delayed Mitogen-Activated Protein Kinase Activity in Human Endothelial Cells via an Autocrine Loop that Involves Basic Fibroblast Growth Factor," Circulation 98:413-421, 1998.

King, S.B. III, et al., "Endovascular β -radiation to Reduce Restenosis after Coronary Balloon Angioplasty: Results of the Beta Energy Restenosis Trial (BERT)," Circulation 97:2025-2030, 1998.

Kolodgie, F.D., et al., "Estradiol Attenuates Directed Migration of Vascular Smooth Muscle Cells *In Vitro*," Am. J. Pathol. 148(3):969-976, 1996.

Kraskinski, K., et al., "Estradiol Accelerates Functional Endothelial Recovery after Arterial Injury," Circulation 95(7):1768-1772, 1997.

Kristinsson, J.K., et al., "Dexamethasone-cyclodextrin-polymer Co-complexes in Aqueous Eye Drops: Aqueous Humor Pharmacokinetics in Humans," Invest. Ophthalmol. Vis. Sci. 37(6):1199-1203, 1996.

Kublick, H., et al., "Nasal Absorption of 17-beta-estradiol from Different Cyclodextrin Inclusion Formulations in Sheep," Eur. J. Pharma. Biopharm. 42(6):320-324, 1996.

Kuiper, G.G.J.M., et al., "Cloning of a Novel Estrogen Receptor Expressed in Rat Prostrate and Ovary," Proc. Natl. Acad. Sci. USA 93:5925-5930, 1996.

Kullo, I.J., et al., "Enhanced Endothelium-dependent Relaxations after Gene Transfer of Recombinant Endothelial Nitric Oxide Synthase to Rabbit Carotid Arteries," Hypertension 30(3):314-320, 1997.

Levine, R.L., et al., "Medroxyprogesterone Attenuates Estrogen-mediated Inhibition of Neointima Formation after Balloon Injury of the Rat Carotid Artery," Circulation 94(9):2221-2227, 1996.

Lindner, V., et al., "Regrowth of Arterial Endothelium: Denudation with Minimal Trauma Leads to Complete Endothelial Cell Growth," Lab. Invest. 61(5):556-563, 1989.

Lindner, V., et al., "Basic Fibroblast Growth Factor Stimulates Endothelial Regrowth and Proliferation in Denuded Arteries," J. Clin. Invest. 85:2004-2008, 1990.

Lindner, V., et al., "Increased Expression of Estrogen Receptor-f3 mRNA in Male Blood Vessels after Vascular Injury," Cir. Res. 83:224-229, 1998.

Losordo, D.W., et al., "Variable Expression of the Estrogen Receptor in Normal and Atherosclerotic Coronary Arteries of Premenopausal Women," Circulation 89(4):1501-1510, 1994.

Ludmer, P.L., et al., "Paradoxical Vasoconstriction Induced by Acetylcholine in Atherosclerotic Coronary Arteries," N. Eng. J. Med. 315(17):1046-1051, 1986.

MacRitchie, A.N., et al., "Estrogen Upregulates Endothelial Nitric Oxide Synthase Gene Expression in Fetal Pulmonary Artery Endothelium," Circ. Res. 81(3):355-362, 1997.

Malekianpour, M., et al., "Abnormal Coronary Vasomotion and Angina after Successful Coronary Angioplasty," Circulation 94(8):I-560, 1996 (Abstract).

Mancini, G.B.J., et al., "Automated Quantitative Coronary Arteriography: Morphologic and Functional Validation *In Vivo* of a Rapid Digital Angiographic Method," Circulation 75(2):452-460, 1987.

McLaren, J., et al., "Vascular Endothelial Growth Factor is Produced by Peritoneal Fluid Macrophages in Endometriosis and is Regulated by Ovarian Steroids," J. Clin. Invest. 98(2):482-489, 1996.

Mendelsohn, M.E. and Karas, R.H., "Estrogen and the Blood Vessel Wall," Curr. Opin. Cardiol. 9:619-626, 1994.

Mikkola, T., et al., "17-Beta-estradiol Stimulates Prostacyclin, but not Endothelin-1 Production in Human Vascular Endothelial Cells," J. Clin. Endocrin. Metab. 80(6):1832-1836, 1995.

Mikkola, T., et al., "Effect of Physiological Concentrations of Estradiol on PGI-2 and NO in Endothelial Cells," 25(2):141-147, 1996.

Morales, D.E., et al., "Estrogen Promotes Angiogenic Activity in Human Umbilical Vein Endothelial Cells In Vitro and in a Murine Model," Circulation 91(3):755-763, 1995.

Mori, T., et al., "Short Term Estrogen Treatment Prior to and Following Balloon Injury of Rat Carotid Artery Effectively Blunts the Vascular Injury Response," J. Am. Coll. Cardiol. 33(2 Suppl. A):267A, 1999 (Abstract).

Mosselman, S., et al., "ER β : Identification and Characterization of a Novel Human Estrogen Receptor," FEBS Let. 392:49-53, 1996.

Moura, A., et al., "Intramural Delivery of Agent Via a Novel Drug-delivery Sleeve: Histological and Functional Evaluation," Circulation 92(8):2299-2305, 1995.

O'Brien, J.E., et al., "Relation Between Estrogen Replacement Therapy and Restenosis after Percutaneous Coronary Interventions," J. Am. Coll. Cardiol. 28(5):1111-1118, 1996.

O'Keefe, J.H., et al., "Estrogen Replacement Therapy after Coronary Angioplasty in Women," J. Am. Coll. Cardiol. 29(1):1-5, 1997.

Oparil, S., et al., "Sexually Dimorphic Response of the Balloon-injured Rat Carotid Artery to Hormone Treatment," Circulation 95(5):1301-1307, 1997.

Perrot-Applanat, M., "Questradiol and Proliferation of Vascular Cells," 54(3):333-337, 1999.

Post, M.J., et al., "The Relative Importance of Arterial Remodeling Compared with Intimal Hyperplasia in Lumen Renarrowing after Balloon Angioplasty," Circulation 89(6):2816-2821, 1994.

Reis, S.E., et al., "Ethinyl Estradiol Acutely Attenuates Abnormal Coronary Vasomotor Responses to Acetylcholine in Postmenopausal Women," Circulation 89(1):52-60, 1994.

Roselli, M., et al., "Circulating Nitric Oxide (Nitrite/Nitrate) Levels in Postmenopausal Women Substituted with 17 β -estradiol and Norethisterone Acetate: A Two-year Follow-up Study," Hypertension 25(2):848-853, 1995.

Sarkar, R., et al., "Nitric Oxide Reversibly Inhibits the Migration of Cultured Vascular Smooth Muscle Cells," Circ. Res. 78(2):225-230, 1996.

Selzman, C.H., et al., "Estrogen Replacement Inhibits Intimal Hyperplasia and the Accumulation and Effects of Transforming Growth Factor Beta-1," J. Surg. Res. 80(2):380-385, 1998.

Seo, K.K., et al., "Involvement of Endothelial Nitric Oxide Synthase in the Impaired Endothelium-dependent Relaxation of Cavernous Smooth Muscle in Hypercholesterolemic Rabbit," J. Androl. 20(2):298-306, 1999.

Shimokawa, H., et al., "Porcine Coronary Arteries with Regenerated Endothelium have a Reduced Endothelium-dependent Responsiveness to Aggregating Platelets and Serotonin," Cir. Res. 61(2):256-270, 1987.

Speir, E., et al., "Estrogen Inhibits Transcription Factor and Cell Adhesion Molecule Activation in Cytokine-stimulated Human Coronary Smooth Muscle Cell via Antioxidant Effects," Circulation Suppl. I:1-220, 1998 (Abstract).

Spyridopoulos, I., et al., Estrogen-receptor-mediated Inhibition of Human Endothelial Cell Apoptosis: Estradiol as a Survival Factor," Circulation 95(6):1505-1514, 1997.

Sullivan, T.R., Jr., et al., "Estrogen Inhibits the Response-to-injury in a Mouse Carotid Artery Model," J. Clin. Invest. 96:2482-2488, 1995.

Tanaka, H., et al., "Sustained Activation of Vascular Cells and Leukocytes in the Rabbit Aorta after Balloon Injury," Circulation 88(4):1788-1803, 1993.

Tanaka, H., et al., "Proliferating Arterial Smooth Muscle Cells after Balloon Injury Express TNF- α but not Interleukin-1 or Basic Fibroblast Growth Factor," Arterioscler. Thromb. Vasc. Biol. 16(1):12-18, 1996.

Teirstein, P.S., et al., "Catheter-based Radiotherapy to Inhibit Restenosis after Coronary Stenting," N. Engl. J. Med. 336(24):1697-1703, 1997.

Varenne, O., et al., "Local Adenovirus-mediated Transfer of Human Endothelial Nitric Oxide Synthase Reduces Luminal Narrowing After Coronary Angioplasty in Pigs," Circulation 98:916-926, 1998.

Venkov, C.D., et al., "Identification of Authentic Estrogen Receptor in Cultured Endothelial Cells: A Potential Mechanism for Steroid Hormone Regulation of Endothelial Function," Circulation 94(4):727-733, 1996.

Weiner, C.P., et al., "Induction of Calcium-dependent Nitric Oxide Synthases by Sex Hormones," Proc. Natl. Acad. Sci. USA 91:5212-5216, 1994.

Wellman, G.C., et al., "Gender Differences in Coronary Artery Diameter Involve Estrogen, Nitric Oxide, and Ca^{2+} -dependent K^+ Channels," Circ. Res. 79(5):1024-1030, 1996.

Williams, J.K., et al., "Short-term Administration of Estrogen and Vascular Responses of Atherosclerotic Coronary Arteries," J. Am. Coll. Cardio. 20(2):452-457, 1992.

Yoon Young-Sup, et al., "Local Intraluminal Infusion of Oestradiol Containing Liposome in Rat Cartoid Balloon Injury Model," Eur. Heart J. 19:616, 1998.

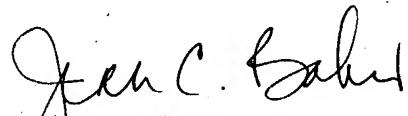
Zhang, Y.-Q., et al., "Effects of Gender and Estradiol Treatment on Focal Brain Ischemia," Brain Res. 784(1/2):321-324, 1998.

No fees are believed necessary to enter this Statement. However, if any fees are necessary please charge Deposit Account 17-0055.

Respectfully submitted,

Baskaran Chandrasekar, et al.

June 23, 2003

By: 

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		Filing Date	June 20, 2003
		First Named Inventor	Baskaran Chandrasekar
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Sheet	1	of	9
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		Akishita, M., et al., "Estrogen Inhibits Cuff-induced Intima Thickening of Rat Femoral Artery: Effects on Migration and Proliferation of Vascular Smooth Muscle Cells," <i>Atherosclerosis</i> 130:1-10, 1997.		
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		Chen, S.J., et al., "Estrogen Reduces Myointimal Proliferation after Balloon Injury of Rat Carotid Artery," <i>Circulation</i> 93(3):577-584, 1996.		
		Chesebro, J.H., et al., "Restenosis after Arterial Angioplasty: A Hemorrhologic Response to Injury," <i>Am. J. Cardiol.</i> 60:10B-16B, 1987.		
		Clowes, A.W., et al., "Kinetics of Cellular Proliferation after Arterial Injury: Smooth Muscle Cell Growth in the Absence of Endothelium," <i>Lab. Invest.</i> 49(3):327-333, 1983.		

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		Collins, P., et al., Hemoglobin Inhibits Endothelium-dependent Relaxation to Acetylcholine in Human Coronary Arteries In Vivo," Circulation 87(1):80-85, 1993.
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		Cornwell, T.L., et al., "Inhibition of Smooth Muscle Cell Growth by Nitric Oxide and Activation of cAMP-dependent Protein Kinase bo cGMP," Am. J. Physiol. 267:C1405-C1413, 1994.
		Currier, J.W. and Faxon, D.P., "Restenosis after Percutaneous Transluminal Coronary Angioplasty: Have We Been Aiming at the Wrong Target?", J. Am. Coll. Cardiol. 25(2):516-520, 1995.
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		Dangas, G., and Fuster, V., "Management of Restenosis after Coronary Intervention," Am. Heart J. 132(2):428-436, 1996.
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		Frijlink, H.W., et al., "The Pharmacokinetics of Beta-cyclodextrin and 2-hydroxypropyl-beta-cyclodextrin in the Rat," Pharm. Res. 7(12):1248-1252, 1990.
		Furchtgott, R.F. and Zawadski, J.V., "The Obligatory Role of Endothelial Cells in the Relaxation of Arterial Smooth Muscle by Acetylcholine," Nature 288:373-376, 1980.

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		First Named Inventor	Baskaran Chandrasekar
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		Geary, R.L., et al., "Conjugated Equine Estrogens Inhibit Progression of Atherosclerosis but have no Effect on Intimal Hyperplasia or Arterial Remodeling Induced by Balloon Catheter Injury in Monkeys," J. Am. Coll. Cardiol. 31(5):1158-1164, 1998.		
		Gilligan, D.M., et al., "Effects of Physiological Levels of Estrogen on Coronary Vasomotor Function in Postmenopausal Women," Circulation 89(6):2545-2551, 1994.		
		Hayashi, Y., et al., "Functional and Anatomical Recovery of Endothelium after Denudation of Coronary Artery," Am. Physiol. Soc. H1081-H1090, 1988.		
		Hayashi, T., et al., "Estrogen Increases Endothelial Nitric Oxide by a Receptor-mediated System," Biochem. Biophys. Res. Commun. 214(3):847-855, 1995.		
		Hishikawa, K., et al., "Up-regulation of Nitric Oxide Synthase by Estradiol in Human Aortic Endothelial Cells," FEBS Let. 360:291-293, 1995.		
		Hoon, T.J., et al., "Bioequivalence of a 17-beta Estradiol Hydroxypropyl-beta-cyclodextrin Complex in Postmenopausal Women," J. Clin. Pharmacol. 33:1116-1121, 1993.		
		Hyder, S.M., et al., "Uterine Expression of Vascular Endothelial Growth Factor is Increased by Estradiol and Tamoxifen," Cancer Res. 56(17):3954-3960, 1996.		
		Iafrati, M.D., et al., "Estrogen Inhibits the Vascular Injury Response in Estrogen Receptor alpha-deficient Mice," Nat. Med. 3(5):545-548, 1997.		
		Karas, R.H., et al., "Human Vascular Smooth Muscle Cells Contain Functional Estrogen Receptor," Circulation 89(5):1943-1950, 1994.		
		Karas, S.P., et al., "Coronary Intimal Proliferation after Balloon Injury and Stenting in Swine: An Animal Model of Restenosis," J. Am. Coll. Cardiol. 20(2):467-474, 1992.		
		Kauffman, R.F., et al., "Comparative Effects of Local vs. Systemic Administration of Estrogen upon Vascular Responses to Balloon Injury," Circulation 92(8):1628, 1995.		

Examiner Signature		Date Considered
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		Kawana, H., et al., "Gender Differences in Improvement of Endothelium-dependent Vasodilation after Estrogen Supplementation," J. Am. Coll. Cardio. 30(4):914-919, 1997.	
		Keany, J.F., et al., "17-Beta-estradiol Preserves Endothelial Vasodilator Function and Limits Low-density Lipoprotein Oxidation in Hypercholesterolemic Swine," Circulation 89(5):2251-2259, 1994.	
		Kim-Schulze, S., et al., "Expression of An Estrogen Receptor by Human Coronary Artery and Umbilical Vein Endothelia Cells," Circulation 94(6):1402-1407, 1996.	
		Kim-Schulze, S., et al., "Estrogen Stimulates Delayed Mitogen-Activated Protein Kinase Activity in Human Endothelial Cells via an Autocrine Loop that Involves Basic Fibroblast Growth Factor," Circulation 98:413-421, 1998.	
		King, S.B., III, et al., "Endovascular Beta-radiation to Reduce Restenosis after Coronary Balloon Angioplasty: Results of the Beta Energy Restenosis Trial (BERT)," Circulation 97:2025-2030, 1998.	
		Kolodgie, F.D., et al., "Estradiol Attenuates Directed Migration of Vascular Smooth Muscle Cells In Vitro," Am. J. Pathol. 148(3):969-976, 1996.	
		Kraskinski, K., et al., "Estradiol Accelerates Functional Endothelial Recovery after Arterial Injury," Circulation 95(7):1768-1772, 1997.	
		Kristensson, J.K., et al., "Dexamethasone-cyclodextrin-polymer Co-complexes in Aqueous Eye Drops: Aqueous Humor Pharmacokinetics in Humans," Invest. Ophthalmol. Vis. Sci. 37(6):1199-1203, 1996.	
		Kublick, H., et al., "Nasal Absorption of 17-beta-estradiol from Different Cyclodextrin Inclusion Formulations in Sheep," Eur. J. Pharma. Biopharm. 42(6):320-324, 1996.	
		Kuiper, G.G.J.M., et al., "Cloning of a Novel Estrogen Receptor Expressed in Rat Prostate and Ovary," Proc. Natl. Acad. Sci. USA 93:5925-5930, 1996.	
		Kullo, I.J., et al., "Enhanced Endothelium-dependent Relaxations after Gene Transfer of Recombinant Endothelial Nitric Oxide Synthase to Rabbit Carotid Arteries," Hypertension 30(3):314-320, 1997.	

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		Levine, R.L., et al., "Medroxyprogesterone Attenuates Estrogen-mediated Inhibition of Neointima Formation after Balloon Injury of the Rat Carotid Artery," Circulation 94(9):2221-2227, 1996.	
		Lindner, V., et al., "Regrowth of Arterial Endothelium: Denudation with Minimal Trauma Leads to Complete Endothelial Cell Growth," Lab. Invest. 61(5):556-563, 1989.	
		Lindner, V., et al., "Basic Fibroblast Growth Factor Stimulates Endothelial Regrowth and Proliferation in Denuded Arteries," J. Clin. Invest. 85:2004-2008, 1990.	
		Lindner, V., et al., "Increased Expression of Estrogen Receptor-f3 mRNA in Male Blood Vessels after Vascular Injury," Cir. Res. 83:224-229, 1998.	
		Losordo, D.W., et al., "Variable Expression of the Estrogen Receptor in Normal and Atherosclerotic Coronary Arteries of Premenopausal Women," Circulation 89(4):1501-1510, 1994.	
		Ludmer, P.L., et al., "Paradoxical Vasoconstriction Induced by Acetylcholine in Atherosclerotic Coronary Arteries," N. Eng. J. Med. 315(17):1046-1051, 1986.	
		MacRitchie, A.N., et al., "Estrogen Upregulates Endothelial Nitric Oxide Synthase Gene Expression in Fetal Pulmonary Artery Endothelium," Cir. Res. 81(3):355-362, 1997.	
		Malekianpour, M., et al., "Abnormal Coronary Vasomotion and Angina after Successful Coronary Angioplasty," Circulation 94(8):1-560, 1996 (Abstract).	
		Mancini, G.B.J., et al., "Automated Quantitative Coronary Arteriography: Morphologic and Functional Validation In Vivo of a Rapid Digital Angiographic Method," Circulation 75(2):452-460, 1987.	
		McLaren, J., et al., "Vascular Endothelial Growth Factor is Produced by Peritoneal Fluid Macrophages in Endometriosis and is Regulated by Ovarian Steroids," J. Clin. Invest. 98(2):482-489, 1996.	
		Mendelsohn, M.E. and Karas, R.H., "Estrogen and the Blood Vessel Wall," Curr. Opin. Cardiol. 9:619-626, 1994.	

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		Mikkola, T., et al., "17-Beta-estradiol Stimulates Prostacyclin, but not Endothelin-1, Production in Human Vascular Endothelial Cells," J. Clin. Endocrin. Metab. 80(6):1832-1836, 1995.
		Mikkola, T., et al., "Effect of Physiological Concentrations of Estradiol on PGI-2 and NO in Endothelial Cells," 25(2):141-147, 1996.
		Morales, D.E., et al., "Estrogen Promotes Angiogenic Activity in Human Umbilical Vein Endothelial Cells In Vitro and in a Murine Model," Circulation 91(3):755-763, 1995.
		Mori, T., et al., "Short Term Estrogen Treatment Prior to and Following Balloon Injury of Rat Carotid Artery Effectively Blunts the Vascular Injury Response," J. Am. Coll. Cardiol. 33(2 Supp. 1): 267A, 1999 (Abstract).
		Mosselman, S., et al., "ERB: Identification and Characterization of a Novel Human Estrogen Receptor," FEBS Let. 392:49-53, 1996.
		Moura, A., et al., Intramural Delivery of Agent via a Novel Drug-delivery Sleeve: Histological and Functional Evaluation," Circulation 92(8):2299-2305, 1995.
		O'Brien, J.E., et al., "Relation Between Estrogen Replacement Therapy and Restenosis after Percutaneous Coronary Interventions," J. Am. Coll. Cardiol. 28(5):1111-1118, 1996.
		O'Keefe, J.H., et al., "Estrogen Replacement Therapy after Coronary Angioplasty in Women," J. Am. Coll. Cardiol. 29(1):1-5, 1997.
		Oparil, S., et al., "Sexually Dimorphic Response of the Balloon-injured Rat Carotid Artery to Hormone Treatment," Circulation 95(5):1301-1307, 1997.
		Perrot-Appanat, M., "Questradiol and Proliferation of Vascular Cells," 54(3):333-337, 1999.
		Post, M.J., et al., "The Relative Importance of Arterial Remodeling Compared with Intimal Hyperplasia in Lumen Renarrowing after Balloon Angioplasty," Circulation 89(6):2816-2821, 1994.

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		Reis, S.E., et al., "Ethinyl Estradiol Acutely Attenuates Abnormal Coronary Vasomotor Responses to Acetylcholine in Postmenopausal Women," Circulation 89(1):52-60, 1994.	
		Roselli, M., et al., "Circulating Nitric Oxide (Nitrite?Nitrate) Levels in Postmenopausal Women Substituted with 17-beta-estradiol and Norethisterone Acetate: A Two-year Follow-up Study," Hypertension 25(2):848-853, 1995.	
		Sarkar, R., et al., "Nitric Oxide Reversibly Inhibits the Migration of Cultured Vascular Smooth Muscle Cells," Cir. Res. 78(2):225-230, 1996.	
		Selzman, C.H., et al., "Estrogen Replacement Inhibits Intimal Hyperplasia and the Accumulation and Effects of Transforming Growth Factor Beta1," J. Surg. Res. 80(2):380-385, 1998.	
		Seo, K.K., et al., "Involvement of Endothelial Nitric Oxide Synthase in the Impaired Endothelium-dependent Relaxation of Cavernous Smooth Muscle in Hypercholesterolemic Rabbit," J. Androl. 20(2):298-306, 1999.	
		Shimokawa, H., et al, "Porcine Coronary Arteries with Regenerated Endothelium have a Reduced Endothelium-dependent Responsiveness to Aggregating Platelets and Serotonin," Cir. Res. 61(2):256-270, 1987.	
		Speir, E., et al., "Estrogen Inhibits Transcription Factor and Cell Adhesion Molecule Activation in Cytokine-stimulated Human Coronary Smooth Muscle Cell via Antioxidant Effects," Circulation Suppl. I:1-220, 1998 (Abstract).	
		Spyridopoulos, I., et al., "Estrogen-receptor-mediated Inhibition of Human Endothelial Cell Apoptosis: Estradiol as a Survival Factor," Circulation 95(6):1505-1514, 1997.	
		Sullivan, T.R., Jr., et al., "Estrogen Inhibits the Response-to-injury in a Mouse Carotid Artery Model," J. Clin. Invest. 96:2482-2488, 1995.	
		Tanaka, H., et al., "Sustained Activation of Vascular Cells and Leukocytes in the Rabbit Aorta after Balloon Injury," Circulation 88(4):1788-1803, 1993	
		Tanaka, H., et al., "Proliferating Arterial Smooth Muscle Cells after Balloon Injury Express TNF-alpha but not Interleukin-1 or Basic Fibroblast Growth Factor," Arterioscler. Thromb. Vasc. Biol. 16(1):12-18, 1996.	

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		Teirstein, P.S., "Catheter-based Radiotherapy to Inhibit Restenosis after Coronary Stenting," N. Engl. J. Med. 336(24):1697-1703, 1997.
		Varenne, O., et al., "Local Adenovirus-mediated Transfer to Human Endothelial Nitric Oxide Synthase Reduces Liminal Narrowing After Coronary Angioplasty in Pigs," Circulation 98:916-926, 1998.
		Venkov, C.D., et al., "Identification of Authentic Estrogen Receptor in Cultured Endothelial Cells: A Potential Mechanism for Steroid Hormone Regulation of Endothelial Function," Circulation 94(4):727-733, 1996.
		Weiner, C.P., et al., "Induction of Calcium-dependent Nitric Oxide Synthases by Sex Hormones," Proc. Natl. Acad. Sci. USA 91:5212-5216, 1994.
		Wellman, G.C., et al., "Gender Differences in Coronary Artery Diameter Involve Estrogen, Nitric Oxide, and Ca ²⁺ -dependent K ⁺ Channels," Circ. Res. 79(5):1024-1030, 1996.
		Williams, J.K., et al., "Short-term Administration of Estrogen and Vascular Responses of Atherosclerotic Coronary Arteries," J. Am. Coll. Cardio. 20(2):452-457, 1992.
		Yoon Young-Sup, et al., "Local Intraluminal Infusion of Oestradiol Containing Liposome in Rat Cartoid Balloon Injury Model," Eur. Heart J. 19:616, 1998.
		Zhang, Y.-Q., et al., "Effects of Gender and Estradiol Treatment on Focal Brain Ischemia," Brain Res. 784(1/2):321-324, 1998.

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